DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Application for New Medical Services and Technologies Seeking to Qualify for Add-On Payments Under the Hospital Inpatient Prospective Payment System for Federal Fiscal Year (FY) 2009

Section 1886(d)(5)(K) authorizes the Secretary to establish a special payment methodology for new medical services and technologies used in inpatient procedures. To qualify for additional payments under this provision; a new technology must represent a substantial clinical improvement; data reflecting the cost of new technology must not yet be available in the data used to recalibrate the diagnosis-related groups (DRGs); and the DRG payment rate otherwise applicable to the new technology would be inadequate (see 42 CFR 412.87 (b)).

DEADLINE

Submit a complete application (see required information below) showing substantial clinical improvement and significant sample of charge data – **No later than November 19, 2007**

Complete database – **No later than December 31, 2007**

An application is considered complete when all of the information requested below has been submitted and when questions related to such information have been answered by the applicant.

REQUIRED INFORMATION

Applications must include the following information (may be entered directly onto this form). CMS may request other information in order to evaluate specific requests. Note that a separate application is required for each distinct item included in a request. For example, if an applicant requests add-on payments for two unique technologies or services, a separate application is required for each technology or service.

1. A completed tracking form. (A tracking form may be downloaded at http://www.cms.hhs.gov/providers/hipps/newtech.asp.)

2. Name, address, and telephone number of primary contact for the application.

3. Trade/brand name of the new technology.

4. Describe the technology fully in general terminology. (What is it? What does it do? How is it used? Also, submit relevant descriptive booklets, brochures, package inserts, as well as copies of published peer-review articles for applications for new medical services and technologies.)

Note: Data provided in this application or in the tracking form may become subject to disclosure. If you are providing data or information that is proprietary or otherwise protected from disclosure under the Trade Secrets Act or Exemption 4 under the Freedom of Information Act, please mark this information as such. CMS will attempt, to the extent allowed by Federal law, to keep this information protected from public view.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) pre-market approval (or expected approval) for the technology or service. Provide a copy of the FDA approval/clearance letter. If approval has not yet been granted, please provide a copy of the approval notice to CMS immediately after it becomes available. List the name and phone number of a contact at the FDA who is knowledgeable about the pre-market approval request for the new technology listed above.

6. Was the product available on the market immediately after FDA approval? If not, please provide the date that the medical service or technology came on the market (i.e. first sales or availability) and an explanation and documentation of any delay (i.e. manufacturing issues, shelf life concerns or other reasons).

7. If the technology is a drug, was/is your FDA application considered under priority review? Refer to http://www.accessdata.fda.gov/scripts/cder/onctools/Accel.cfm for more details.

8. If the technology is a device, is there an investigational device exemption (IDE) number from the FDA assigned to the device? If yes, please provide this code. Refer to http://www.fda.gov/cdrh/devadvice/ide/index.shtml for more details. What class (I, II, or III) was/is assigned to the device? Refer to http://www.fda.gov/cdrh/devadvice/313.html for more details.

9. Does the service or technology have an existing International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code or is an application pending? Refer to http://www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/01_overview.asp#TopOfPage for more details. We note that, if the product were to receive add-on payment status approval, it would need to be distinctly identifiable by ICD-9-CM code(s) in the MedPAR claims data in order to receive add-on payment.

10. Has the service or technology received a Healthcare Common Procedure Coding System (HCPCS) code? If yes, when was it approved? What is the code? Refer to http://www.cms.hhs.gov/MedHCPCSGenInfo/01_Overview.asp#TopOfPage for more information.

11. Have you submitted an outpatient application for pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. Refer to

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http://www.cms.hhs.gov/HospitalOutpatientPPS/04_passthrough_payment.asp#TopOfPage for more information.

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of the lesser of 75 percent of the standardized amount increased to reflect the difference between costs and charges or 75 percent of 1 standard deviation beyond the geometric mean standardized charge for all cases in the DRGs to which the new technology is assigned. Table 10 from the annual final rule lists the thresholds by DRG. The most recent version of Table 10 can be downloaded at: http://www.cms.hhs.gov/AcuteInpatientPPS/Downloads/table10_1488n.pdf

Charge Information

12. What is the (anticipated) average standardized charge per case involving this new technology? (Please refer to the technical appendix at the end of this application on how to standardize charges)

13. Please describe the type of data used to calculate the average standardized charge? (i.e. number of cases [Medicare or non-Medicare], number of providers, time period from which data was collected).

a. What DRGs are affected by this new technology? Note: For applicants with cases prior to October 1, 2007, use the CMS-DRGs and download the crosswalk of CMS- DRGs to MS- DRGs at http://www.cms.hhs.gov/acuteinpatientpps/downloads/CrosswalkCMSDRGtoMSDRG.zip. For cases on of after October 1, 2007, use the MS-DRGs. Applicants should list both CMS and MS- DRGs for this question. Assistance in determining the correct DRG assignment can be obtained through a local hospital where the procedure is being performed, or by contacting the Division of Acute Care, CMS for assistance (Tiffany.Swygert@cms.hhs.gov or Michael.Treitel@cms.hhs.gov).

b. What is the anticipated volume of this technology for FY 2008 (by DRG)?

14. Please provide all data used to calculate charges and standardized charges per case involving the new technology (in electronic format).

Cost Information

15. What is the (current and/or anticipated) cost of the technology to the hospital, per patient?

16. Please provide a breakdown how the cost of the technology is calculated (i.e. for drugs, the average dosage or number of units per patient (ml/kg/hr); for devices, a breakdown of

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the cost of all of the new technology components used per patient, clearly showing which components are the "new" ones).

Clinical Improvement

17. Describe in detail how the new service or technology represents a substantial clinical improvement over existing services or technologies.

18. Describe relevant clinical trial(s), including dates and findings.

19. Provide a list and copies of published peer-review articles relevant to the new service or technology.

WHERE TO SEND APPLICATIONS

Mail **ten (10)** copies of each completed application to the following address:

Inpatient PPS New Medical Services and Technologies
Division of Acute Care
Mailstop C4-08-06
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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Technical Appendix

Standardizing Charges

Note: We standardize charges in order to compare charges equally amongst all hospitals. Standardized charges are charges per case minus the wage index, indirect medical education (IME) and disproportionate share hospital (DSH). The formula below explains how to calculate standardized charges per case.

Note: Use all values (DSH, IME etc…) from the appropriate fiscal year the claim is being submitted from including the Labor and Non Labor share percentage. Also, different percentages may apply for hospitals with a wage index over or under 1 depending on the fiscal year.

Step 1: Total Adjusted Charges (TAC) = Total Charges / (1 + IME Operating Adjustment Factor + DSH Operating Adjustment Factor)

Step 2: Standardized Charge = TAC/ ((**Labor Share %** * ^wage index value) + (Non Labor Share Percentage * COLA))

Example for claims being submitted from FY 2006

Step 1: Total Adjusted Charges (TAC) = Total Charges / (1 + ^IME Operating Adjustment Factor + ^DSH Operating Adjustment Factor)

Step 2: Standardized Charge = TAC/ ((**.697 for hospital with Wage Index > 1 or .62 for hospitals with Wage Index < 1** * ^wage index value) + (**.303 for hospital with Wage Index > 1 or .38 for hospitals with Wage Index < 1** * COLA))

Definition Key

COLA is always equal to 1, except for hospitals in Alaska and Hawaii
^Note: These values are hospital specific
IME, DSH and Wage Index values by provider can be downloaded from our Public Use Files at:
http://www.cms.hhs.gov/providers/hipps/ippspufs.asp

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